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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/970,146	10/02/2001	Eric G. Lovett	279.262US1	9587

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 08/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/970,146	Applicant(s) LOVETT ET AL.	
	Examiner Kennedy Schaetzle	Art Unit 3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 17 May 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3-10,12-14,16,21-23,26,28,29,33,38,39,41-43,45-48,50,51 and 57 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 02 October 2001 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/25/02</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,11,15,17-20,24,25,27,30-32,34-37,40,44,4 and 52-56.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of claims 1, 3-10, 12-14, 16, 21-23, 26, 28, 29, 33, 38, 39, 41-43, 45-48, 50, 51 and 57 in the reply filed on May 17, 2004 is acknowledged. Although the applicants state in the first paragraph of the Remarks that the election is without traverse, they appear to nonetheless argue the restriction requirement in paragraph 3 of page 2. The applicants state that the examiner has not identified any species according to MPEP § 809.02(a). The examiner has clearly identified the *distinguishing characteristics* of the species as required by section §809.02(a) in the list provided in paragraph 1 of the Office Action dated November 21, 2003. It is the examiner's opinion that such a listing is wholly sufficient for the applicants --who should be intimately aware of their own invention-- to identify a single species not containing mutually exclusive distinguishing characteristics. Furthermore, the applicants' assertion that claims 1, 23 and 38 are generic is not agreed with. A generic claim must be generic to *all* species (see MPEP §806.04(d)).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

3. Claims 9, 16, 22, 23, 28 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Bakels et al. (Pat. No. 5,800,497).

Regarding claim 9, Bakels et al. disclose an elongated device body 5, at least one assembly coupled with the device body (cavities 75, 76, etc., for containing a rheometric material), and a rheometric material (the magnet-rheologic fluid, MRF). The examiner considers the MRF to inherently contract and/or stiffen when electrical current is applied to it. The applicants define rheometric materials for the purposes of the invention to include magneto-rheological fluids, and state that rheometric materials experience a stiffness change when small amounts of current or magnetic field are applied. It is further noted that Bakels et al. refer to the same supplier –Lord Corporation (see col. 3, line 55)—as referred to by the applicants.

Concerning claim 22, the examiner considers the device body of Bakels et al. to have a preformed curved portion such as shown in cross-section in Figs. 4 and 8.

Regarding claim 23, the examiner considers the assembly to include not only the cavities mentioned in the rejection of claim 9 above, but also the winding of material shown as coil 101 in Fig. 6.

In regards to claim 28, comments made above in the rejection of similar limitations apply here as well. Specifically regarding the means for electrically stiffening the at least one assembly, the examiner considers the application of an electromagnetic stylet as disclosed in col. 5, lines 8-10 to constitute such means. The applicants disclose on lines 14 and 15 of page 23 that the creation of a magnetic field via a conductor equates to electrical activation.

4. Claims 1, 3-6, 8-10, 12-14, 16, 21-23, 26, 28, 29, 33, 38, 39, 41-43, 45-48, 50, 51 and 57 are rejected under 35 U.S.C. 102(e) as being anticipated by Maseda (Pat. No. 6,514,237).

Regarding claim 1, the examiner considers the conductive platinum metal discussed in col. 5, lines 1-19 to constitute at least one electrode with the electroactive polymer representing the rheometric material electrically coupled to the electrode. Platinum is considered to be capable of transmitting and receiving electrical signals to and from tissue due to its conductive and biocompatible nature.

Regarding claim 3, note col. 6, lines 4-7.

Regarding claim 4, since the noble metal platinum electrode is deposited within the network of the ionic polymer, the examiner considers the rheometric material to be surrounding the electrode and thus can be said to be on an outer layer of the electrode.

Regarding claims 5 and 6 and claims with similar limitations, one can arbitrarily designate one side of the catheter body to constitute a first surface with the opposite side of the body constituting a second surface. Since the rheometric material can be attached to the body such as set forth in col. 5, lines 56-67, one strand or electrode (note the rejection of claim 1) can be placed in a groove on one side of the catheter, while another strand or electrode is placed in a groove on the opposite side.

Claim 9 is clearly anticipated.

Regarding claim 10 and claims with similar limitations, note col. 5, lines 50-55.

Claims 23 and 28 are clearly anticipated.

Regarding claim 38, note the comments made in the rejection of claim 1 above as it pertains to the use of an electrode.

Regarding claim 41, Maseda teaches that the multiple assemblies may be independently controlled (as well as individual strip components in each assembly) so as to perform any number of complex maneuvers such as wiggling, slithering, twisting, etc., etc.. Such control necessitates selective application of energy to each assembly at different times.

Claim 50 is clearly anticipated.

Concerning claim 51, complicated movements such as wiggling, slithering, twisting, etc., inherently require pulsing of the electric current to alternately stiffen and relax portions of the device body.

Regarding claim 57, note the rejection of claim 22 above. Fig. 2 of Maseda shows a pre-curved device body.

Claim Rejections - 35 USC § 102/103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 1, 5, 7, 38, 42, 43 and 45-48 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Bakels et al. (Pat. No. 5,800,497).

With reference to claims 1 and 38, in Fig. 6 Bakels et al. show the distal tip of an electrode lead wherein a rheometric material 106 is disposed at the distal end for stiffening at least a portion of the lead body via applied energy. Although Bakels et al. do not explicitly refer to cap assembly 105 as an electrode, the construction shown is well-known in the medical lead arts to relate to a distal tip electrode, with conductor coil 101 electrically attached thereto for supplying electrical energy to the electrode. Given that all the other leads disclosed by Bakels et al. comprise distal electrodes and given the showing of a conductor coil 101 abutting the cap 105, those of ordinary skill in the art would have recognized the cap to equate to an electrode, with the rheometric material electrically coupled by contact and contained therein. In any event the examiner takes Official Notice that the use of cap electrodes on the distal ends of medical electrical leads is old and well-known by those of ordinary skill in the art. To employ a conductive electrode cap would have therefore been considered a matter of obvious design dependent upon the particular application of use.

Regarding claim 42, the examiner considers the coil such as shown in Fig. 6 to be wound around an axis of the body.

Regarding claim 43, the examiner considers energy to be applied to an assembly disposed at a distal end of the body when a pacing pulse is applied to the distal tip electrode.

Regarding claim 45, Fig. 8 shows assemblies 90 disposed on at least two sides of the device body. Voltage is selectively applied to the conductors when it is desired to stimulate the heart.

In regards to claim 46, the stiffness of the lead is selectively varied when one chooses to solidify the MRF fluid or liquefy.

Concerning claim 47, Bakels et al. teaches that the lead body will be moved when the MRF fluid is solidified within the heart (note the text abridging cols. 3 and 4).

Regarding claim 48, the examiner considers the device body to be braced against movement by virtue of the fact that fibrotic growth fixes the lead body in place as per the discussion in col. 4, lines 1-26.

Claim Rejections - 35 USC § 103

7. Claims 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bakels et al. (Pat. No. 5,800,497).

Regarding claim 41, although Bakels et al. do not elaborate on the timing of the application of electrical energy to the at least one assembly, the examiner takes Official Notice that it is old and well-known by those of ordinary skill in the pacer arts that dual-chamber pacemakers (note col. 3, lines 1-7) apply energy to respective assemblies (the examiner considers an assembly to comprise a conductor coil) at different times such as for example, when pacing both the atrium and the ventricle with an intermediate AV delay period.

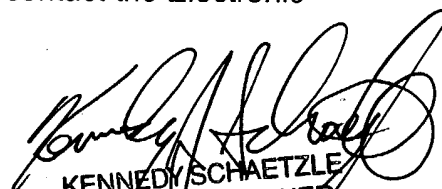
Conclusion

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy Schaetzle whose telephone number is 703 308-2211. The examiner can normally be reached on 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 703 308-0851. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


KENNEDY SCHAETZLE
PRIMARY EXAMINER
8-17-04